



UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/782,320	02/13/2001	Bernhard H. van Lengerich	BVL-102A	9819

7590
Douglas J. Taylor, Esq.
General Mills, Inc.
P.O. Box 1113
Minneapolis, MN 55440

04/28/2009

EXAMINER

ROBERTS, LEZAH

ART UNIT	PAPER NUMBER
----------	--------------

1612

MAIL DATE	DELIVERY MODE
-----------	---------------

04/28/2009

PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No. 09/782,320	Applicant(s) VAN LINGERICH, BERNHARD H.	
	Examiner LEZAH W. ROBERTS	Art Unit 1612	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 04 December 2008.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) See Continuation Sheet is/are pending in the application.
- 4a) Of the above claim(s) 94 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 25-31, 34, 35, 37-40, 42, 46, 50, 52-59, 61, 62, 64-67, 69, 70, 73, 75, 79, 81-85, 91-93, 95-97, 101, 103, 105, 108 and 109 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date <u>22 Jan 2009</u> . | 6) <input type="checkbox"/> Other: _____ |

Continuation of Disposition of Claims: Claims pending in the application are 25-31,34,35,37-40,42,46,50,52-59,61,62,64-67,69,70,73,75,79, 81-85, 91-97, 101, 103, 105, 108 and 109.

DETAILED ACTION

Applicants' arguments, filed December 4, 2008, have been fully considered. Rejections and/or objections not reiterated from previous office actions are hereby withdrawn. The following rejections and/or objections are either reiterated or newly applied. They constitute the complete set presently being applied to the instant application.

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Response to Arguments in Regards to the Status of Claims

In regard to Applicant's arguments pertaining to election of species of claims 26 and 50, the arguments are persuasive insofar as claims 26 and 50 encompass the same subject matter as the examined, pending claim 53. Examination has been extended to claims 26 and 50.

In regard to the originally elected species durum wheat, the examiner disagrees with Applicant's assertion that the species is allowable. Although the previous examiner has extended prosecution to starch, the rejections set forth below encompass the originally elected species and the claims read on species other than durum wheat. Therefore the claims are not allowable.

Status of Claims: 25-31, 34, 35, 37-40, 42, 46, 50, 52-59, 61, 62, 64-67, 69, 70, 73, 75, 79, 81-85, 91-97, 101, 103, 105, 108 and 109 are pending.

Claim 94 is withdrawn.

Claims

Claim Rejections - 35 USC § 112 - Indefiniteness

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 25, 27-31, 34, 35, 37, 38, 42, 46, 52-59, 61, 62, 64-67, 69, 70, 73, 75, 79, 82, 83, 91-93 and 95-97 were rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. The rejection is maintained and further applied to claims 26, 50, 108 and 109.

Applicant's Arguments to "at least about"

Applicant argues the term "at least about" is not indefinitely inherent and does not contain conflicting terms. Those skilled in the art would know that the term "at least about 40% by weight" would mean that number or more, for example 39% or more than 39% by weight. There is no conflict seen in the term as alleged by the Examiner. Infringement could clearly be assessed by weighing the final product, and determining or analyzing the weight of the matrix material in the final product. Clear guidance is given in the present specification to those skilled in the art to employ an effective

Art Unit: 1612

encapsulating amount of matrix material as recited in the present specification at page 12 second full paragraph, and the examples and Table 2 at page 42 give specific ranges for amounts. This argument is not persuasive.

Examiner's Response

The term "about" permits flexibility, particularly where there is nothing in the record to indicate the precise metes and bounds of the term. See, e.g., Amgen v. Chugai, 18 USPQ2d 1016 (Fed. Cir. 1991); see also MPEP 2173.05 [R-6] A. The scope of term may be considerable where the components of the respective compositions merely perform substantially the same function in substantially the same manner. See, e.g., Conopco v. May, 24 USPQ2d 1721, 1736 (U.S. District Court, Eastern District of Missouri 1992), where a four-fold increase was permitted. By adding the term "least", it cannot be determined where the lower limit lies. Further the claims are drawn to a matrix material in general and the instant specification discloses several matrix materials with ranges that vary from material to material. It cannot be determined if "at least about" 40 encompasses 10% as in the case for cyclodextrin or 5% for guar. Therefore the term "at least about" is indefinite.

Applicant's Arguments in regards to "substantially"

The term "substantially" is well accepted in the art in conjunction with another term to describe a particular characteristic of the claimed invention. The terms objected to by the Examiner are sufficiently definite in view of the general guidelines contained in

Art Unit: 1612

the specification. See In re Mattison. One of ordinary skill in the art would know what was meant by the terms. See Andrew Corp. v. Gabriel Electronics. The present specification provides clear guidance to those skilled in the art as to mixing and extrusion conditions for obtaining a substantially homogenous mixture and to obtaining a substantially non-expanded, non-cellular structure at, for example, page 22 line 12 to page 27 line 3, and page 29 lines 9-13 where exemplary specific densities are provided.

Examiner's Response

The term “substantially” incorporates a degree of variation that has not been defined in any limiting way by Applicant. Since “homogeneous”, “non-expanded” and “non-cellular” are definite phrases, and includes some inherent degree of variation insofar as a perfectly “homogenous” composition and a perfectly “non-expanded” and “non-cellular” structure is merely an ideal, it is unclear what modifying function the term “substantially” serves in this context.

Claim Rejections - 35 USC § 103 – Obviousness (New Rejection)

1) Claims 25-31, 34, 35, 37-40, 46, 50, 52-59, 61, 62, 64-67, 69, 73, 75, 79, 81-83, 85, 91, 92, 93, 95-97, 101, 103, 105, 108 and 109 are rejected under 35 U.S.C. 103(a) as being unpatentable over Lentz et al. (EP 4 404 727) in view of Newton et al. (4,938,967).

Lentz et al. disclose thermoplastic polymer compositions comprising a destructure starch and a polymer comprising a hydroxyl group (component b). The

Art Unit: 1612

compositions further contain additives as well as hydrophobic, substantially water-insoluble polymers (Abstract). Thermoplastic starches have the ability to be extruded and molded into numerous useful shapes and profiles (page 2, lines 37 and 38). The starches are blended with hydrophobic thermoplastic materials and show a surprising increase in all or a part of their physical properties and behavior of their melts. They show an improved dimensional stability in humid air whilst retaining a surprisingly high degree of disintegration in contact with moisture water which in consequence leads to a high degree of biodegradability (page 3, lines 13-20). The starches comprise water and the water is present when the compositions are made, meeting the limitation of water as a plasticizer. Starches used may be extracted from wheat or may be gelatinized or cooked starches (page 4, lines 23-28). The content of water in the starch ranges from 5 to 40% by weight of the starch (page 4, lines 47-49). The hydrophobic polymer, component c, includes polyvinyl acetate (page 6, lines 14-16). The starch component to components b and c ranges from 1:99 to 99:1. Starch comprises preferably 70% to 99% of the mixture (page 6, lines 45-51). Additives include plasticizers, soy proteins, animal gelatin, vegetable gelatin and fatty acids. Hydrophilic polymers such as soy proteins and gelatin may comprise up to 50% of the composition based on the weight of the starch (page 8). Fats comprise up to 5% of the composition (page 9, lines 1-3). Additives also include antioxidants (page 9, line 6), encompassing claim 46. The compositions may be formed into granules and powder. They may act as carriers for active agents such as pharmaceuticals and/or agriculturally active compounds such as insecticides or pesticides for subsequent release application of these ingredients. These

Art Unit: 1612

components may be mixed into the compositions, thus encompassing a homogeneous mixture.

The reference differs from the instant claims insofar as it does not disclose the size of granules made from the compositions or the amount of active agent in a granule.

Newton et al. is used as a teaching to show the general conditions of the art when formulating pharmaceutical compositions. The dosages are preferably capsules that contain one or more units. Density of conventional tablets and pellets is usually about 1.0 to 1.5 g/ml (1000 to 1500 g/liter) (col. 1, lines 11-13), encompassing claim 34. Selection of the binder determines the rate of release of the active ingredient (col. 1, lines 19-21). The dosage may be a plurality of pellets having a dimension below about 2 mm. The pellets have a shape that is spherical (col. 7, lines 48-57). The active ingredient comprises 0.0001 to 45% of the compositions (col. 10, lines 30-35). Various active agents may be used such as tonics (encompassing claim 93), anti-inflammatory enzymes and anti-viral agents (col. 13 to col. 14, line 48). The pellets may comprise a matrix binder and a coating. These serve to control the release of the active. Binders include polymers such as starch (col. 8, lines 53-68). The reference differs from the instant claims insofar as it does not disclose a plasticized matrix is used in the disclosed dosage forms.

It would have been obvious to formulate capsules comprising pellets or granules when formulating pharmaceutical compositions with the matrices of the primary reference motivated by the desire to formulate a conventional dosage form with conventional parameters such as the density, as disclosed by the secondary reference.

In regards to the amounts recited in the instant claims such as the amount of matrix material, this is a result effective variable. The matrix material controls the release of the active and the active results in achieving the desired effect for the desired treatment. That being said, it would take no more than routine skill in the art to adjust the amount of binder in the pellets to achieve the desired active release profile including the amount of active released in an aqueous or gastric juice environment as recited in claims 38 and 65.

In regards to the active, the secondary reference discloses the active may comprise 0.0001 to 45% of the compositions. The prior art does not disclose the exact claimed values, but does overlap: in such instances even a slight overlap in range establishes a *prima facie* case of obviousness. In re Peterson, 65 USPQ2d 1379, 1382 (Fed. Cir. 2003). Therefore it would have been obvious to have used 1 to 85%, 5% to 50%, 3% to 50% and 5% to 20% of encapsulant (active agent) consistent with the In re Peterson decision.

It would have been obvious to have coated the actives before incorporating them into the matrix of Lentz et al. motivated by the desire to add an additional control release mechanism for the active agent as suggested by the teachings of Newton et al.

2) Claims 42, 69, 70, 84, 108 and 109 are rejected under 35 U.S.C. 103(a) as being unpatentable over Lentz et al. (EP 4 404 727) in view of Newton et al. (4,938,967) in further view of Jane et al. (US 5,397,834).

Lentz et al. and Newton et al. differ from the instant claims insofar as they do not disclose the wheat used as a starch source is durum wheat.

Jane et al. disclose biodegradable thermoplastic components made of the reaction of a starch aldehyde with protein. Suitable starches include those derived from durum wheat (col. 4, lines 41-50). The reference differs from the instant claims insofar as it does not disclose the thermoplastic compositions are formulated into discrete particles comprising an active agent.

Generally, it is *prima facie* obvious to select a known material for incorporation into a composition, based on its recognized suitability for its intended use. See MPEP 2144.07. It would have been obvious to one of ordinary skill in the art to have used wheat durum as the starch source in the compositions of the combined teachings of Lentz et al. and Newton et al. motivated by the desire to use a source comprising starch suitable for making thermoplastic compositions as disclosed by Jane et al. and supported by MPEP 2144.07.

Claims 25, 27-31, 34, 35, 37-40, 42, 46, 52-59, 61, 62, 64-67, 69, 70, 73, 75, 79, 81-85, 91, 92, 93, 95-97, 101, 103, 105, 108 and 109 are rejected.

Claims 26, 50 and 94 are withdrawn.

No claims allowed.

Conclusion

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to LEZAH W. ROBERTS whose telephone number is (571)272-1071. The examiner can normally be reached on 8:30 - 5:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Frederick F. Krass can be reached on 571-272-0580. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Art Unit: 1612

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Lezah W Roberts/
Examiner, Art Unit 1612

/Frederick Krass/
Supervisory Patent Examiner, Art Unit 1612